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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,537	09/22/2003	C. Richard Schlegel	082137-0306009	5934

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,537	SCHLEGEL ET AL.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16,17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16,17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Claims 14, 16, 17, and 20 are present.

Raw Sequence Listing have been entered.

PRELIMINARY AMENDMENT

The receipt of preliminary amendments, filed 2/6/04 is acknowledged.

Claim Rejections - 35 USC 112

Claims 14, 16, 17, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, and 17 are indefinite for recitations of "effective amount," this is a relative terminology since it is not clear what applicants consider to be effective. The claims have been interpreted in light of the specification, and since the specification lacks teaching with regard to prophylactically effective amount the claims are considered to be indefinite. This affects the dependent claims 16, and 20.

In addition, claim 14 is indefinite for recitation of "extract", the claim has been interpreted in light of the specification and since the specification does not set forth what the

intended "extract" can be, the claim is considered to be vague and indefinite. The intended metes and bounds of the "extract" is not defined. Is a piece of L1 intended? Is the intent to administer a piece of tumor extract to individuals?

Claim Rejections - 35 USC 112

Claims 14, 16, 17, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method and composition of formalin inactivated L1 protein of papillomavirus being utilized as a therapeutic vaccine, does not reasonably provide enablement for human papillomavirus composition and method of conferring prophylactic protection against all types of human papilloma viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification is deficient in providing teaching with regard to the broad scope of the claimed invention. At the onset applicants are reminded that this field is highly unpredictable with regard to prophylactic vaccine and method of induction of prophylactic response. The recited human papilloma viruses are vastly different one from the other in their mode of infection, type of tissues and induction of neoplasia. The specification fails to provide adequate and reasonable teaching with regard to prophylactically effective amount of formalin-inactivated human papillomavirus L1 protein within the scope of the claimed invention. Furthermore, the specification fails to provide adequate teaching with regard to extensive claimed method of protection against all types of papilloma viruses with varied etiologies, and sequence homologies. It is well known to those in the relevant art that prophylactic immunity to a wide range of papilloma viruses is type-specific (see Jarrett et al, 1990, abstract, and page 475, left column). Hence, the COPV results cannot be

extrapolated to all types of human papilloma viruses that have different form of infection and target different tissue site(s). Moreover, it is well known to those ordinary skilled in the relevant art that formalin-inactivated viruses may induce atypical resistance to infection, after perhaps initial positive response, due to antigenic folding and un-availability of antigenic epitopes (see Murphy et al, 1990, page 480, left column). In addition, the mode of administration, the regiments of effective amounts have not been discussed. There are no teachings that the claimed methods and composition would induce the prophylactic effect envisioned within the broad scope of the invention. Still further, applicants are reminded that although the literature now supports the notion of therapeutic vaccine wherein the vaccine comprises L1 protein of human papillomavirus (HPV) to induce a therapeutic response against the said virus, the literature to date does not support the prophylactic vaccine for protection of human papillomavirus before the onset of the infection (see Fife K., Australasian Journal of Dermatology, 1998, vol. 39 Suppl 1S8-10, see the abstract, and page S9, right column). The state of the art regarding a prophylactic vaccine for HPV does not even support as how the HPV infects cells, or whether antibody alone is sufficient to induce protection or whether CTL is required, yet applicants claim they have provided adequate teaching as far back as 1995, this should be reconciled. Applicants are more than welcome to provide evidence of pre or posts filing that provide the state of the art showing prophylactic vaccine results directed against HPV. In essence, the prophylactic vaccine of the invention claims that an individual who is not yet infected with HPV may receive a dose of the formalin inactivated L1 protein prior to the onset of the human papillomavirus and at sometime in the future when and if that individual becomes infected with human papillomavirus the individual would induce a sufficient and appropriate immune response to eliminate the virus

and completely protect the individual from infection. The specification has not provided adequate teaching regarding a prophylactic vaccine. There is no teaching as to what type of immune response would be required or is induced for a sufficient prophylactic response, whether a Th1 or Th2 response is required, these are not simple issues that can be glossed over. In addition, it is well known that formalin treated antigens stimulate unbalanced immune response and the antibodies might be directed to non-protective epitopes (see Murphy et al, 1990, page 481, left column, middle of first paragraph) which means that if the non-infected individual were to get infected in the future even if he/she induces antibodies against the virus the antibodies might not be targeted against the appropriate epitopes to protect the individual. Hence, to fully enable the scope of the invention absent applicants□ disclosure one of ordinary skill in the art would be required to conduct undue experimentation. Therefore, one ordinary skilled in the art would be required to conduct large quantity of experimentations to practice the full scope of the claims. The scope of the claims are directed to prophylactic vaccine, Applicants have general statements regarding the prophylactic vaccine. However with regard to an unpredictable field, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of a prophylactic vaccine for members of human papillomavirus. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on

the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321□ may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 16, 17, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/134,377. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Free of Prior Art

Claims 14, 16, 17, and 20 are deemed free of prior art, given failure of the prior art to teach or reasonably suggest the formalin inactivated L1 of human papillomavirus to be utilized as a prophylactic vaccine and its method of administration.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571 272-1600.

A. R. Salimi

2/27/2004